OCT 18 2006

K061549

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

Irvine Scientific Sales Co., Inc.
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Contact: Wendell Lee, Pharm. D.

Date Submitted: June 2, 2006

Device Identification:

Trade Name:	AmnioStat-FLM-PG
Common Name:	AmnioStat
Classification Name:	Lecithin/Sphingomyelin Ratio in Amniotic Fluid (21 CFR, 862.1455)

Predicate Device:

AmnioStat-FLM (K822150), Lecithin/Sphingomyelin ratio in amniotic fluid test system (21 CFR 862.1455)

Description:

The AmnioStat-FLM-PG Kit is an immunological semi-quantitative agglutination test for determining the presence of phosphatidylglycerol in human amniotic fluid at concentrations indicative of fetal lung maturity. The AmnioStat-FLM-PG Kit is comprised of five (5) components and a disposable agglutination cards (cardboard with laminate). The five (5) components that comprise the kit include three (3) kit controls, Negative Control, Catalog #91013, Low Positive Control, Catalog #91027, High Positive Control, Catalog #91028, two (2) reagents, Reagent A, Catalog #91012 and Reagent B, Catalog #91029, and one (1) Buffer, Catalog #91011.

The three (2) controls (negative, low positive, and high positive) in the AmnioStat-FLM-PG Kit are run with each test. The AmnioStat-FLM-PG Kit can be used to run six (6) patient test samples. Each patient sample is run on an individual agglutination card with a set of controls. Please refer to the photographs of the AmnioStat-LM-PG Kit presented in **Appendix D** of the submission.

The AmnioStat-FLM-PG Kit is a next generation kit based upon the same immunological agglutination test as AmnioStat-FLM (K822150) previously cleared for marketing. The immunological agglutination reaction is the same between the AmnioStat-FLM (K822150) and the AmnioStat-FLM-PG kit. The AmnioStat-FLM-PG Kit incorporates the use of Sudan Black B into one of the kit reagents which makes the differentiation of the three (3) kit controls more distinguishable. The AmnioStat-FLM (K822150) is performed on a glass slide that requires the use of a mirror to distinguish and differentiate the kit controls based upon clarity of the background and the size of the agglutinated particles. The AmnioStat-FLM-PG is performed on a disposable agglutination card that is white and does not require the use of a mirror to distinguish and differentiate the kit controls.

Intended Use:

AmnioStat-FLM-PG is intended for use as an immunologic semiquantitative agglutination test for determining the presence of phosphatidylglycerol in human amniotic fluid at concentrations indicative of fetal lung maturity.

The AmnioStat-FLM-PG test kit is to be used by laboratory personnel in a hospital and/or clinical laboratory.

Performance Data:

The AmnioStat-FLM-PG Kit has been evaluated by five (5) independent field laboratories that currently use the AmnioStat-FLM test kit. The response

and feedback from the laboratories that evaluated the kit indicates it was well received in terms of its application, ease of use, and effectiveness in the determining fetal lung maturity in human amniotic fluid.

In addition, clinical comparison data was also generated for seventy-three (73) patient samples that were tested between the two (2) clinical laboratories. The results of the comparison study yielded no false positive test results and demonstrated that the AmnioStat-FLM-PG kit performs in accordance with the intended use of the product.

Additional Information:

Functionality of the three (3) kit controls (negative, low positive, and high positive) in the AmnioStat-FLM-PG Kit with regards to differentiation in appearance is performed as a condition of release. Please refer to the proposed labeling presented in **Section 14** of this submission.

Conclusion:

The results from the field testing of this product demonstrates that the AmnioStat-FLM-PG Kit is suitable for its intended use, meets the criteria as outlined in 21 CFR Section 862.1455, Lecithin/Sphingomyelin ratio in amniotic fluid test system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Wendell Lee, Pharm.D.
Vice President Regulatory Affairs
Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588

OCT 18 2006

Re: k061549
Trade/Device Name: AminoStat-FLM-PG
Regulation Number: 21 CFR 862.1455
Regulation Name: Lecithin/sphingomyelin ratio in amniotic fluid test system
Regulatory Class: Class II
Product Code: JHG
Dated: September 25, 2006
Received: September 26, 2006

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061549

Device Name: AmnioStat-FLM-PG

Indications For Use:

The AmnioStat-FLM-PG Kit is intended to be used for the immunological detection of phosphatidylglycerol (PG) in amniotic fluid to determine fetal lung maturity of the fetus collected from transabdominal or vaginal pool samples.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061549